Equine Practice Annual Index

Volume 16, Numbers 1 - 10, 1994

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NADA #101-479, Approved by FDA.

Banamine®
(FLUNIXIN MEGLUMINE)
Solution 50 mg/mL
Veterinary
For Intravenous Use or Intramuscular Use in Horses Only

CAUTION Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION Each milliliter of BANAMINE contains flunixin meglumine equivalent to 50 mg flunixin, 0.1 mg edetate disodium, 2.5 mg sodium formaldehyde sulfoxylate, 4.0 mg diethanolamine, 207.2 mg propylene glycol; 5.0 mg phenol as preservative, hydrochloric acid, water for injection q.s.

ACTIVITY Flunixin meglumine is a potent, nonnarcotic, nonsteroidal, analgesic agent with anti-inflammatory and antipyretic activity. It is significantly more potent than pentazocine, meperidine and codeine as an analgesic in the rat yeast paw test. Flunixin is four times as potent on a mg per mg basis as phenylbutazone as measured by the reduction in lameness and swelling in the horse. Plasma half-life in horse serum is 1.6 hours following a single dose of 1.1 mg/kg. Measurable amounts are detectable in horse plasma at 8 hours post injection.

TOXICITY Toxicity studies were conducted in horses. A threefold intramuscular dose of 1.5 mg per pound of body weight daily for 10 consecutive days was safe. No changes were observed in hematology, serum chemistry, or urinalysis values. Intravenous dosages of 0.5 mg/lb daily for 15 days; 1.5 mg/lb daily for 10 days; and 2.5 mg/lb daily for 5 days produced no changes in blood or urine parameters. No injection site irritation was observed following intramuscular injection of the 0.5 mg/lb recommended dose. Some irritation was observed following a 3-fold dose administered intramuscularly.

INDICATIONS BANAMINE is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

It is also recommended for the alleviation of visceral pain associated with colic in the horse.

DOSE AND ADMINISTRATION The recommended dose for musculoskeletal disorders is 0.5 mg per pound (1 mL/100 lbs) of body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days. Studies show onset of activity is within 2 hours. Peak response occurs between 12 and 16 hours and duration of activity is 24–36 hours.

The recommended dose for the alleviation of pain associated with equine colic is 0.5 mg per pound of body weight. Intravenous administration is recommended for prompt relief. Clinical studies show pain is alleviated in less than 15 minutes in many cases. Treatment may be repeated when signs of colic recur. During clinical studies approximately 10% of the horses required one or two additional treatments. The cause of colic should be determined and treated with concomitant therapy.

CONTRAINDICATIONS There are no known contraindications to this drug when used as directed. Intra-arterial injection should be avoided. Horses inadvertently injected intra-arterially can show adverse reactions. Signs can be ataxia, incoordination, hyperventilation, hysteria, and muscle weakness. Signs are transient and disappear without antidotal medication within a few minutes. Do not use in horses showing hypersensitivity to flunixin meglumine.

PRECAUTIONS The effect of BANAMINE on pregnancy has not been determined. Studies to determine activity of BANAMINE when administered concomitantly with other drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring adjunctive therapy. Isolated reports of local reactions following intramuscular injection, particularly in the neck, have been received. These include localized swelling, sweating, induration, and stiffness.

WARNING Isolated reports of local reactions following intramuscular injection, particularly in the neck, have been received. These include localized swelling, sweating, induration, and stiffness. In rare instances, fatal or nonfatal clostridial infections or other infections have been reported in association with intramuscular use of BANAMINE Solution. In addition, rare instances of anaphylactic-like reactions, some of which have been fatal, have been reported primarily following intravenous use.

Not for use in horses intended for food.

SIDE EFFECTS For adverse reactions that have been reported following the use of BANAMINE Solution, see **WARNING** section.

HOW SUPPLIED BANAMINE Solution, 50 mg/mL, is available in 50 mL and 100 mL multidose vials.

Store between 2° and 30°C (36° and 86° F).

FEBRUARY 1991

Schering-Plough Animal Health Corp.
Kenilworth, New Jersey 07033

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